JUN - 3 2003

K030640

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Solutions USA, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: February 26, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens MicrO2+
Nellcor N-45

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Oximeter	74 DQA	II	870.2700
Ear Oximeter	74 DPZ	II	870.2710

Legally Marketed Device Identification:
MICRO2+, 510(k) K012770

Description of Modification:

The release of software version VA1 includes a re-labeling of the MicrO2+ and the recognition of Nellcor OxiMax sensors. The modifications implemented with the release of software version VA1 have not altered the basic fundamental technology of the MicrO2+. Testing with VA1 software indicates no new issues relative to safety and efficacy.

Intended Use:
The MICRO2+ is intended for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate during both no motion and motion conditions, and for patients who are well or poorly perfused, using a range of compatible sensors. The device will produce visual and aural alarms if these parameters vary beyond preset limits

Assessment of non-clinical performance data for equivalence: See Section J

Assessment of clinical performance data for equivalence: See Section J

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Section J

Siemens Medical Solutions USA, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
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Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

Ms. Penelope H. Greco
Siemens Medical Solutions USA, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K030640
Trade/Device Name: Siemens MicrO2+ with VA1 Software
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 23, 2003
Received: May 27, 2003

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030640

Device Name: **Siemens INFINITY MICRO2+**

Indications for Use:

The MICRO2+ is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate during both no motion and motion conditions, and for patients who are well or poorly perfused.

MRI Compatibility Statement:
The Siemens INFINITY MICRO2+ is not intended for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: k030640